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10/552,485	03/19/2008	Yoshimasa Sakamoto	082368-006500US	1941

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EXAMINER	
MACFARLANE, STACEY NEE	

ART UNIT	PAPER NUMBER
1649	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,485	SAKAMOTO ET AL.	
	Examiner	Art Unit	
	STACEY MACFARLANE	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-44* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 21, 22, in so far as it is drawn to a polynucleotide probe comprising a sequence complementary to a sequence of SEQ ID NO: 1.

Group II, claim(s) 1, 21, 22, in so far as it is drawn to a polynucleotide probe comprising a sequence complementary to a sequence of SEQ ID NO: 2.

Group III, claim(s) 1, 21, 22, in so far as it is drawn to a polynucleotide probe comprising a sequence complementary to a sequence encoding the protein of SEQ ID NO: 3.

Group IV, claim(s) 1, 21, 22, in so far as it is drawn to a polynucleotide probe comprising a sequence complementary to a sequence encoding the protein of SEQ ID NO: 4.

Group V, claim(s) 1, 21, 22, in so far as it is drawn to a polynucleotide probe comprising a sequence of at least 15 contiguous nucleotides from SEQ ID NO: 1.

Group VI, claim(s) 1, 21, 22, in so far as it is drawn to a polynucleotide probe comprising a sequence of at least 15 contiguous nucleotides from SEQ ID NO: 2.

Group VII, claim(s) 2, 18, 19, 23, 24, 25, drawn to a method for selecting dopaminergic progenitor cells comprising contacting said cell with a polynucleotide probe.

Group VIII, claim(s) 3, drawn to a method for selecting dopaminergic progenitor cells comprising using at least one nucleotide probe and a marker for a post-mitotic dopaminergic neuron.

Group IX, claim(s) 4, 12, 20, 28 and 29, drawn to a dopaminergic neuron progenitor cell or population thereof.

Group X, claim(s) 5, 13, drawn to a method for isolating a dopaminergic neuron progenitor cell-specific gene comprising detecting and isolating said gene from said cells.

Group XI, claim(s) 6, 14, drawn to a method of screening compounds that regulate dopaminergic neuron lineage by detecting changes in the proliferative state of the cells.

Group XII, claim(s) 7-9, and 30-33, in so far as it is drawn to an antibody against the polypeptide of SEQ ID NO: 3 encoded by SEQ ID NO: 1.

Group XIII, claim(s) 7-9 and 30-33, in so far as it is drawn to an antibody against the polypeptide of SEQ ID NO: 4 encoded by SEQ ID NO: 2.

Group XVI, claim(s) 10, 26, 27 and 34-38, in so far as it is drawn to a method for selecting a dopaminergic progenitor cell comprising contacting said cell with an antibody raised against the polypeptide of SEQ ID NO: 3 encoded by SEQ ID NO: 1.

Group XVII, claim(s) 10, 26, 27 and 34-38, in so far as it is drawn to a method for selecting a dopaminergic progenitor cell comprising contacting said cell with an antibody raised against the polypeptide of SEQ ID NO: 4 encoded by SEQ ID NO: 2.

Group XVIII, claim(s) 11, drawn to a method for selecting dopaminergic progenitor cells comprising using an antibody and a marker for a post-mitotic dopaminergic neuron.

Group XIX, claim(s) 15, 39 and 40, drawn to a kit for treating a neurodegenerative disease comprising a dopaminergic neuron proliferative progenitor cell.

Group XX, claim(s) 16 and 41-42, drawn to a method for treating a neurodegenerative disease comprising transplanting a dopaminergic neuron proliferative progenitor cell into the brain of a patient.

Group XXI, claim(s) 17 and 43-44, drawn to use of a dopaminergic neuron proliferative progenitor cell in the manufacture of a kit for treating Parkinson's disease.

The inventions listed as Groups I-XXI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: a general inventive concept that permeates the groups are polynucleotides comprising SEQ ID NO: 1 and

sequences complementary to these. The expression "special technical feature" is defined in Rule 13.2 as meaning those technical features that define a contribution which each of the inventions makes over the prior art. Whether a particular feature makes a contribution over the prior art, is considered with respect to novelty and inventive step. In the instant application, the polynucleotides comprising SEQ ID NO: 1 and sequences complementary thereto, do not make a contribution over the prior art. SEQ ID NO: 1 is drawn to the polynucleotide sequence encoding the mouse Lrp4/Corin gene which was published in the following prior art (Okazaki et al., "Analysis of the mouse transcriptome based on functional annotation of 60,770 full-length cDNAs", Nature, 240(6915):563-573, December 5, 2002). The prior art recites the common technical feature of Groups I-XXI, thus, there is no special technical feature over the prior art and the application lacks Unity of Invention under PCT Rule 13.1.

Furthermore, pursuant to 37 C.F.R. § 1.475 (a), Unity of invention before the International Searching Authority, an international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). When an application contains claims drawn to different categories of inventions, such as in the instant application where claims are drawn to multiple methods and products, 37 C.F.R. § 1.475 (b) states that unity of invention exists if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

The inventions of Groups I-XXI are drawn to multiple materially distinct methods and structurally distinct products. Thus, as claimed these inventions of the instant application do not fall into one of the combinations that the ISA/US considers as supporting unity of invention.

2. The inventions are independent or distinct, each from the other because: Inventions of Groups I-VI, IX, XII, XIII and XIX are directed to related products. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed Inventions I-VI, IX, XII, XIII and XIX are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function, each having an distinct and independent utility, and the inventions are not disclosed as being usable together or interchangable. Furthermore, the products of Inventions I-VI, IX, XII, XIII and XIX do not reflect a single inventive concept because they do not share a common feature or

combination of features that distinguishes them as a group from prior art. For example, the polynucleotides of Groups I through VI and the antibodies of Groups XII and XIII are patentably distinct for the following reasons. Antibodies are structurally distinct from polynucleotides, comprising IgG with 2 heavy and 2 light chains containing constant and variable regions, including framework regions which act as a scaffold for the 6 complementary determining regions (CDRs). Polynucleotides are composed of nucleic acids. Any relationship between a polynucleotide and antibody is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide antigen. In the present claims, the polynucleotides of Group I-VI do not encode for the antibodies of Groups XII and XIII. Therefore, the antibody and polynucleotide are patentably distinct. Likewise, the cells of Group IX and the kit of Group XIX are structurally distinct from each other and from the polynucleotide or antibody inventions. Searching the inventions of Groups I-VI, IX, XII, XIII and XIX together would impose a burden upon the examiner and the resources of the Office, since a search of on of the polynucleotides could not be used to determine the patentability of any antibody, cell or kit invention. Searching the inventions of Groups I-VI, IX, XII, XIII and XIX together would impose a serious search burden because the antibodies, polynucleotides, cells and kits are not coextensive. Additionally, in cases such as this one where distinct descriptive sequence information is provided, the sequences are searched in appropriate databases, thus, SEQ ID NOs: 1-4 could not be searched together. The inventions of Groups I-VI, IX, XII, XIII and XIX are each patentably distinct.

Inventions VII, VIII, X, XI, XVI-XVIII, XX and XXI are directed to related processes. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are directed to different methods that recite structurally and functionally distinct elements, are not required one for the other, achieve different goals, and therefore constitute patentably distinct inventions. The instant specification does not disclose that these methods would be used together. The methods of Groups VII, VIII, X, XI, XVI-XVIII, XX and XXI are all unrelated as they comprise distinct steps and utilize different products that demonstrate each method has a different mode of operation. Each invention performs a different function using structurally and functionally divergent material. Moreover, the methodology and materials necessary for screening compounds differ significantly from the methodology and materials required for treatment of disease comprising cell transplantation. Searching the inventions of Groups VII, VIII, X, XI, XVI-XVIII, XX and XXI together would impose serious search burden as the searches for each claimed method are not coextensive. Prior art which teaches a method for selecting cells would not necessarily be applicable to the methods of treating disease, for example. For these reasons the Inventions VII, VIII, X, XI, XVI-XVIII, XX and XXI are patentably distinct.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement

may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

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Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Species Election

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

The structurally distinct polynucleotide probes listed in claim 1, for example.

The structurally distinct antibodies listed in claim 7, for example.

The distinct cells from those listed in claim 39, for example.

For the inventions of Groups VII, VIII, IX, X, XVIII and XIX-XXI, Applicant is required, in reply to this action, to elect a single species from those above to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or

corresponding special technical features for the following reasons: Claims drawn to any these species would have the distinct characteristics of said species, there is nothing of record to indicate these polynucleotides, cell types and antibodies to be obvious variants of one another, thus, the species are not so linked so as to form, as a group, a unified inventive concept within the art. The polynucleotides recited are each structurally distinct and a search of a methods comprising one polynucleotide is not coextensive with a method comprising another. The same is true of prior art which teaches any one antibody; or any one cell type along the continuum of dopaminergic neuronal differentiation from progenitor cell lineage.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STACEY MACFARLANE whose telephone number is (571)270-3057. The examiner can normally be reached on M-R 5:45 to 3:30, TELEWORK-Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stacey MacFarlane
Examiner
Art Unit 1649

/Stacey MacFarlane/
Examiner, Art Unit 1649